

MEMO

**TO: Debbie Schechter, Office of Community Involvement, Superfund Division**  
**via fax: 415-744-1796**

**cc:** Keith Takata, Superfund Division Director  
Kevin Mayer, Superfund Division, Region 9 perchlorate contact

**FR:** Catherine McCracken  
c/o Banff Springs Hotel - Tel: 403-762-2211, room 911  
(at this number until 11/17; possibly until 11/18)

**DT:** November 14, 1999

**RE:** Perchlorate and schedule for updated reference dose on perchlorate

-----

Debbie,

→ I would appreciate it if you would make copies of this fax and provide to Keith and Kevin.

As we discussed last week, there have been some recent developments related to perchlorate, including the notification to Region 9 of Dr. Ross Brechner's study and the 10/22/99 request from OSWER and OW to NCEA to provide an updated reference dose on perchlorate by the Spring of 2000. In my capacity as the perchlorate contact within OCI, I feel it is appropriate to direct my input and recommendations to your attention. I have attempted to identify what I think are key factors that may need to be considered in the decision making process. Any recommendations I am making or options I am suggesting are in an effort to support what I believe must be the overall goal of the EPA: producing a credible, scientifically sound, protective, and defensible updated reference dose on perchlorate. My comments focus on technical/scientific, process, and communications/coordination issues regarding perchlorate. I have attempted to be specific while at the same time providing background information that might be helpful.

I do want to be clear that these are my opinions only and I am hoping that they will help us answer the three questions I always ask my project managers about the EPA's programs and decisions:

1) what are we doing? 2) why are we doing it? and 3) how are we going to get there?

If you have any questions or want to discuss, please leave me a message at -2182 as I am checking voicemail daily while here at the conference. The sessions run from 8:30-4:30pm Monday and Tuesday, and from 8:30-2:30 on Wednesday, but I am available anytime that is convenient for you. I am also in the office Monday through Wednesday of next week if we need to meet to discuss.

Thank you.

*Catherine*

## 1. Technical/Scientific Issues

a. Background The proposed revised oral human health risk benchmark stated in the draft NCEA assessment was 0.0009 mg/kg-day. If the standard adult model weight (70kg) and water consumption levels (2 L/day) are used to calculate a Drinking Water Equivalent Level (DWEL), the resulting DWEL is 31.5ppb. The peer reviewers of the draft assessment concluded that the RfD proposed by the EPA is likely to be conservative. ORD issued an interim guidance memo (6/18/99, also noted in the June 3, 1999 cover memo to the external peer review report transmitted by OSWER) recommending that EPA "risk assessors and risk managers continue to use the standing provisional RfD range of 0.0001 to 0.0005 mg/kg-day for perchlorate-related assessment activities." If this range is converted to a DWEL using the standard adult assumptions, the resulting DWEL value are 4-18 ppb. DWELs calculated using infant or child weight and water consumption assumptions under either the proposed benchmark or the standing provisional RfD range, result in DWEL values close to, or below the current detection limit for perchlorate. These DWELs would be close to, or below the current concentrations of perchlorate in Lake Mead, the Colorado River, and at the intakes for the MWD and the Central Arizona Project at Lake Havasu, CA, and other locations.

The standing provisional RfD issued by the NCEA Superfund Technical Support Center based on assessments in 1992 and revised in 1995 is based on what most agree would be a very limited database of information. No cancer assessment had been performed when the revision was made in 1995. The draft NCEA assessment for perchlorate was developed under the EPA's new cancer guidelines.

Most of what we do know about the toxicity of perchlorate is as a result of work done since 1997 (when the analytical methods were developed to lower the detection limits for perchlorate to 4ppb). The majority of this work has been funded by the DoD and/or the Perchlorate Study Group. In September 1999, NCEA estimated that the earliest completion date for the scientific studies identified by the external peer review panel is June 2000, with a revised draft assessment ready to be released for peer review by the Fall of 2000. The final peer review would take place in the winter of 2000/2001, with a final harmonized oral human health risk benchmark for perchlorate to be available in early 2001. The second peer review is intended to be part of the IRIS process and after any revisions are made to the assessment based on the peer reviewers' recommendations, the final assessment would go through the IRIS consensus review process.

Following the establishment of the final benchmark, a Health Advisory would be developed by OW. It is important to recognize that a DWEL assumes that all perchlorate exposure comes from drinking water. The contribution of perchlorate from other sources is considered in the development of a Health Advisory.

### b. Sufficiency of existing information to issue a final updated oral human health risk benchmark:

The external peer review report on the draft NCEA assessment identified a number of different areas for the EPA to address in its next revision of the document. While the Pathology Working Group (PWG) review of the thyroid slides was noted as a top priority, it was not identified as the only issue that required additional work or clarification by the EPA. I have quoted several sections of the peer review report below to emphasize this point, and would encourage full

review of section 3.0 (*Reviews of Toxicity Database, Toxicological Review Document, and Additional Testing Needs by Assigned Panel Members*) when considering this issue. While the peer reviewers did state that the proposed benchmark value is likely to be conservative, I think it is important to note that none of the peer reviewers were willing to make a definitive statement at the peer review meeting when directly asked by an EPA staff member what they would see as an appropriate number.

(Hazard Identification section, page 2-1): "This document summarizes the published data, as well as data that have just been accumulated on perchlorate. We were also informed about further data that are being collected and not yet thoroughly evaluated. In general, the presentation of these results by EPA staff was well done. However, the reviewers want to emphasize that the data that have recently been collected need to be thoroughly evaluated, and that all data should be published in peer-reviewed journals. There was consensus that the thyroid tissue slides from several studies need to be evaluated by a "pathology working group." There was also concern with quality control of TSH measurements across the studies."

"There were a number of statistical issues that need to be addressed by the EPA....Despite these statistical issues it is clear that the numerous studies have delineated the hazards of perchlorate quite nicely. Perchlorate does not appear to produce toxic effects to most organs and is not mutagenic. Insufficient data has been collected to determine its effect on the immune system; however, these studies are in progress."

(Mode of Action section, page 2-2): "If the thyroid hormones are low during development of the central nervous system, mental retardation can result, so-called "cretinism" in humans.....(later paragraph) Thyroid hormones are required for normal mental development. Therefore, when perchlorate inhibits the uptake of iodide by the thyroid gland during the development of the central nervous system during the pre- and early post-natal period, it results in a decrease in thyroid hormones in the blood necessary for normal mental development....(later in paragraph) data sets relating to higher serum T3 and T4 levels in ammonium-perchlorate treated rats, such as in the Neurobehavioral Developmental Study, must be interpreted cautiously."

(Special Populations paragraph, page 2-3): "It is well known that thyroid hormones are essential for the normal development of the central nervous system. Therefore, it was suggested that the effects of perchlorate on mental development during fetal development, as well as in the first few weeks of life be closely evaluated by histopathological, morphological, and behavioral assessments. Also infant exposures to perchlorate, reduced iodide concentrations, and/or alterations in maternal hormones in the mother's milk should be determined. In addition, it should be ascertained whether perchlorate is transferred in significant dosages from mother to pup via the milk."

(Risk Assessment/General Issues paragraph, page 2-3): "...pharmacokinetic/toxicokinetic data of perchlorate in rats and humans will be available for building physiologically-based pharmacokinetic (PB-PK) models to decrease the uncertainty of extrapolating data from laboratory animals to humans. Thus, a predictive risk assessment for perchlorate is possible and should be pursued in the next iteration of this assessment."

(Ecological Assessment paragraph, page 2-4): "The major weakness of the screening ecological assessment were limited data on exposure and the potential for long-term chronic effects."

(Conclusions paragraph, page 2-4): "It is not possible at this time to determine what uncertainty factor should be applied (sic) in the RfD derivation. The magnitude of the uncertainty factor needs to wait until all the relevant studies are complete. Based on the lack of demonstrated adverse effects, the RfD proposed by the EPA (0.0009 mg/kg/day) is likely to be conservative.

(Ecotoxicity Studies section 3.8, page 3-34): "Defining the concentrations of perchlorate that occur in surface waters, sediments, soils, and the tissues of plants and animals clearly is the most important data gap currently. The current information on exposure is so meager that it is impossible to judge the ecological problem posed by perchlorate, if one exists. The lack of this information makes it impossible to decide what types of fish, wildlife, and plants are at risk. The latter is important for making the risk assessments more specific and to guide testing needs."

Note: additional ecotoxicological testing needs for perchlorate are identified on pages 3-40 and 3-41

(Risk Analysis section 3.9, summary paragraph, page 3-42): "Many of the studies upon which this hazard characterization is based are in the process of completion and several important recommendations for further analysis of the results were provided at the review. These new data should be forthcoming over the next several months and will almost assuredly influence the final RfD. It appears premature to offer a firm number in this current hazard characterization document. The chances are great that any provisional RfD will have to be changed within the next 6 to 9 months. While such a provisional standard could be set today, it would be better to postpone promulgation of a single number until the data set is completed and analyzed. An alternative would be to offer a range of RfD values depending on choices of LOAELs, LOELs, BMDs, and uncertainty factors."

(General paragraph, page 3-43): "With the new cancer guidelines, it will be important that the EPA conduct several mode of action based risk assessments in order to take an informed position on the manner in which these new guidelines should be implemented. This example with perchlorate is the first such effort by the US EPA staff. While there is room for improvement and clarification in the document, as noted below, US EPA staff deserves to be commended for taking this important first step under the new guidelines."

c. Perchlorate in Fertilizers and Plants: ORD/NERL in Athens, GA is participating in an interagency/industry joint investigation of perchlorate in fertilizers in light of the significant variations in perchlorate levels reported to date. NERL's finding of detectable levels of perchlorate in nine brands of fertilizer tested has been reported in ES&T, Science News, presented at the American Chemical Society perchlorate symposium, and will be presented at the Society for Environmental Toxicology and Chemistry (SETAC) conference this month. The Fertilizer Institute has raised technical concerns regarding NERL's analytical work on the fertilizer samples and at this time, these results should be considered as preliminary only. ORD/NERL scientists have also investigated perchlorate uptake in different kinds of plants as part of phytoremediation studies. These preliminary studies in the lab and greenhouse have found that some plants break down perchlorate while others can take up perchlorate and accumulate it for a period of time in their leaves, stems, and roots. Again, these results (also being presented at SETAC) should be considered as preliminary only and ORD has stated that "whether agricultural plants grown under typical field conditions accumulate perchlorate from fertilizers or irrigation water is not yet known."

I am fairly confident in saying that even these preliminary studies regarding perchlorate in fertilizer and plants were not part of the information reviewed by the peer review panel. As I

understand it, these preliminary findings do not represent a sufficient information base for the EPA to evaluate if there are any risks to the public from perchlorate in fertilizers or plants. It seems critical that additional work be done in this area prior to the next revision of the assessment, so that potential additional routes of exposure are defined. Specific studies ("farm-gate" analysis and others) to fill these data gaps were defined in April 1999, and I believe are part of the studies that would be completed by June 2000 with DoD and/or PSG funding.

As noted above, the EPA-OW would consider contribution of perchlorate from other sources in developing a Health Advisory.

## **2. Process Issues**

a. EPA policy or practice on revision of toxicity estimates: I believe clarification on this point may be necessary as there appear to be conflicting statements regarding this issue between the 6/18/99 ORD interim guidance memo and the 10/22/99 request from OSWER and OW to NCEA to provide an updated reference dose on perchlorate by the Spring of 2000. My understanding from the interim guidance memo is that until the IRIS consensus review process is complete, existing values remain in effect. The interim guidance also noted that "EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differs from this guidance where appropriate. EPA may change this guidance in the future." The clarification that we may need to make is under what types of circumstances the EPA has adopted, would develop, or would issue revised or interim reference doses under an alternate process (i.e. not using the IRIS consensus review process). If we use our discretion to adopt a case-by-case basis approach, I think it will be important for us to define the criteria for making such a decision.

b. Adoption of action levels/development of health goals: Four states have established action levels for perchlorate: California (18ppb), Nevada (18ppb as a recommended action level for cleanup), Arizona (31ppb as a provisional Health Based Guidance Level) and Texas (32 ppb, revised in the Summer of 1999 to 22ppb, based on exposure assumptions for children). California recently postponed issuing a draft PHG for perchlorate for public comments. ATSDR is in the process of developing a perchlorate health goal. These agencies are using and interpreting information provided in the draft assessment and from other sources to independently make these decisions. I recognize that having a variety of action levels is confusing to most stakeholders, and is having impacts on cleanup decisions. However, I do not know if the EPA would be providing any clarity to this issue if an updated reference dose is provided by the Spring of 2000 or an interim standard implemented. This may be particularly true if additional studies are underway or completed at that same time. A number of requests to delay the first peer review meeting were submitted to the EPA for this reason and I believe it is likely that we would encounter the same issues under a Spring 2000 schedule.

c. Information Base and Decision Making: It is a given that we will never have perfect information about the toxicity of perchlorate. It is also accepted that we know a great deal more about perchlorate and have more data on perchlorate than many chemicals. The EPA appears to have much of the necessary information needed to update the reference dose for perchlorate, but we may need to discuss whether our information base is sufficient to provide an updated reference dose by the Spring of 2000. The difference in timing between the two options identified is 6-9 months.

An additional example of pending data is the American Water Works Association Research

Foundation (AWWARF) survey which is to characterize possible perchlorate contamination of drinking water sources in areas of high risk.

I do think it is reasonable, appropriate, and important for the EPA to establish and meet an overall time line for this process, with identified milestones and decision points, including a deadline for data submissions for consideration in the second revision of the toxicological assessment. I see this time line as critical to us internally, and when communicating externally with other agencies and stakeholders. We are at a disadvantage if we cannot communicate clearly on this point.

### **3. Communication/Coordination Issues**

a. Internal Communication/Coordination: It is essential that the various regions and programs within the EPA be communicating and coordinating on perchlorate issues on a regular basis. Although there is significant individual communication between various staff, I see a need to have a regularly scheduled conference call meeting with follow up notes distributed via Lotus Notes so that those who cannot be on a call are aware of new developments. This is important so that information can be shared, staff can be informed, and we can be more effective in anticipating/reacting to specific needs. A calendar of meeting dates and times developed now for the next six months is easier to manage than trying to determine people's availability every time a call is necessary. I believe that this would also meet the specific request of made by OSWER that NCEA update them on a monthly basis. I would recommend that we identify a HQ press office and congressional affairs point of contact to participate on these calls. In addition, I recommend that Region 9 request copies of the actual plant studies and other work being conducted by NERL in Athens, GA. We have received requests for copies of these studies and we need to clarify if these studies can be released.

b. External Communication/Coordination-IPSC: The Interagency Perchlorate Steering Committee was created to facilitate information exchange and coordination on perchlorate issues. The IPSC now has representatives from 23 different federal, tribal, state, and local government agencies. The IPSC has an Executive Committee, and the following subcommittees: health/toxicology, occurrence, ecotoxicology/transport and transformation, analytical methods, treatment technologies and communications and outreach (which I am on). The peer review subcommittee was eliminated from the IPSC structure this year. We have not had a conference call meeting for a number of months and it is my recommendation that a calendar of meeting dates and times be developed now for the next six months for this group as well. There is a need to develop a master contact list for agency representatives and distribute it to all agencies.

c. External Communication/Coordination-Other: At the R9 tribal conference, Kevin Mayer provided an update on perchlorate to the tribal officials who are in the process of forming the Lower Colorado River Tribal Water Consortium. The five tribes who are on the Lower Colorado River (Cocopah Tribe, Colorado River Indian Tribes, Fort Mojave Tribe, Chemehueve Tribe, and the Quechan Tribe) are members of the IPSC, and tribal officials/staff have made important contributions at stakeholder forums and technical meetings such as the "eco-summit" in April 1999. Overall there are a total of 68 tribes who have interests in Lower Colorado River water issues. I think that we need to determine a strategy to keep this specific group of stakeholders up to date on perchlorate developments.

Region 9 is working to complete the document set necessary to produce a CD-ROM of the

perchlorate peer review report document, which will include the draft assessment and many of the references and reports used to develop the draft assessment. We have indexed a number of perchlorate related documents at the Records Center and at this point, probably have the most comprehensive collection of perchlorate materials.

I am working with Rachel Sakata of OW to create updated material for the EPA's perchlorate web site. This work has not moved forward recently because of the timing issues and schedule options discussion.

I have the information necessary to create an IPSC mailing list database, which includes all individuals who attended the perchlorate stakeholder forums in Henderson, NV, Phoenix, AZ, and Salt Lake City, UT, as well as other interested individuals. I think it would be appropriate to provide information to this group once the timing issues/schedule have been confirmed. I have heard from at least one state agency representative that they would like the IPSC to organize another stakeholders forum since there have been so many different developments in the last year.

d. Dr. Brechner's study: Kevin Mayer and I have briefed you, Paula Bruin, and Brent Maier on recent perchlorate developments, and specifically on Dr. Brechner's study. I feel that this has the potential to become a very visible/high concern issue and I think we need to develop a communications strategy soon with OCGR. Lois Grunwald who had been designated as the press officer for perchlorate issues is no longer with Region 9, and Paula Bruin will only be in the office another couple of weeks prior to being on leave. It would be helpful for me and Kevin to know who we can work with to develop a communications strategy. Dr. Brechner will be here on November 29 to provide us with a briefing on the study and also a copy of the study that can be reviewed by the appropriate EPA staff. Kevin Mayer is coordinating a technical briefing (inviting NV-DEP, CA-DHS, CA-OEHH, ATSDR, and other agencies) and a senior management briefing.

-End-

# FAX

Date: 11/15/99  
No. of pages including this one: 8

To:

Debbie SchuchterUSGA - OCIPhone: 415-744-2178Fax: 415-744-1796

From:

Catherine M'CrackenXerox Business ServicesPhone: (403) 762-1757Fax: (403) 762-1759

Debbie -

Please see attached. A meeting has been scheduled ~~B~~ for Friday 11/19 to discuss the OSWGR/OW request to NCGA to provide an updated RFO for perchlorate by the Spring of 2000. I believe that Kevin Mayer and Keith Takata (and perhaps others in (R9)) have been invited to participate. Please let me know if you have any questions. Thanks,

Catherine

P.S. R6 is sending a copy of their response to the 10/22/99 memo to Kevin Mayer.